Docket No: AHP92021-8-D6 Application No: 10/721629

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## Remarks

Claims 1-7 and 9-14 were pending in this case. Claims 1-7 and 9-14 were rejected.

Claims 1, 2, 4, 7 and 11 are rejected under the judicially created doctrine of obviousness-type double patenting over Claim 30 of U.S. Patent No. 7,001,920 and Claim 41 of U.S. Patent No. 6,673,838. Without addressing the merit of the rejection, in order to facilitate the prosecution of the current case, Applicants acknowledge that a terminal disclaimer may be used to overcome a rejection for non-statutory double patenting upon a finding that all other rejections have been overcome.

Claims 1-7 and 9-14 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement because it was maintained that the specification does not teach a method of treating bulimia nervosa in a mammal. Applicants respectfully traverse the rejection.

To satisfy the written description requirement under 35 U.S.C § 112, first paragraph, Applicants must only show that a skilled artisan would be able to practice the instant invention without undue experimentation. Applicants respectfully maintain that one skilled in the art, with Applicants disclosure before him or her, would be able to practice the claimed invention without undue experimentation. For instance, Pope et al., cited by the Examiner, teaches the use of a variety of antidepressants for the treatment of bulimia and states that, "The dose and plasma levels of antidepressant required to treat bulimia seem to be the same as those required to treat major depression." As stated in the Office Action, the specification does teach a method of treating obesity by administering venlafaxine. As described in the specification (page 8, lines 21-24), the administered dosages of venlafaxine were well within the dosage range prescribed for the use of venlafaxine to treat depression.

Claims 1-5, 7 and 9-13 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Pope et al. in view of Schweizer et al. because it was maintained that one skilled in the art would have been motivated to substitute venlafaxine for another antidepressant in a method of treating bulimia. Applicants respectfully traverse this rejection.

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As the Examiner has aptly noted, the medical treatment arts are highly unpredictable. Different antidepressants act via different mechanisms and one cannot predict whether or how a given antidepressant will work. Pope et al. describe the use of a number of known antidepressants from a variety of drug classes including tricyclics and monoamine oxidase inhibitors for the treatment of bulimia. However, unlike the claimed compound, venlafaxine, none of the drugs discussed in Pope et al. are serotonin reuptake inhibitors, norepinephrine reuptake inhibitors or combined norepinephrine and serotonin uptake inhibitors (SNRIs). The compounds discussed in Pope et al. act by mechanisms different than the compounds of the presently claimed method. Since the presently claimed method defines the administation of compounds neither taught nor suggested by Pope et al., the reference provides no reasonable expectation of success for the claimed method. The mere teaching of Schweitzer et al. that venlafaxine is an antidepressant does not overcome the deficiencies of Pope et al. In view of the foregoing, Applicants maintain that Claims 1-5, 7 and 9-13 are not rendered obvious in light of Pope et al. in view of Schweizer et al. and respectfully request that the rejection be withdrawn.

Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Pope et al. in view of Schweizer et al. and further in view of Wang. Wang teaches that the disposition of venlafaxine enantiomers in humans is not steroselective. Applicants point out that Claim 6 does not relate to stereoselectivity but rather defines the position of  $R_5$  and  $R_6$  on the phenyl ring relative to the point of attachment. Nothing in Wang overcomes the deficiencies of Pope et al. and Schweizer et al. described above and Applicants respectfully request that this rejection be withdrawn.

Claims 1-5, 7 and 9-14 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Pope et al. in view of Edgren et al. Applicants respectfully traverse this rejection. Edgren et al. teaches controlled release dosage forms. Edgren et al. does not teach the use of venlafaxine for the treatment of bulimia. Nothing in Edgren et al. remedies the deficiencies of Pope et al. described above and Applicants respectfully request that this rejection be withdrawn.

Claim 6 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Pope et al. in view of Edgren et al. and further in view of Wang. Wang teaches that the disposition of venlafaxine enantiomers in humans is not stereoselective. As explained above, Applicants point out that Claim 6 does not relate to stereoselectivity. Nothing in Wang overcomes the

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deficiencies of Pope et al. and Edgren et al. described above and Applicants respectfully request that this rejection be withdrawn.

In view of the foregoing, Applicants respectfully maintain that Clams 1-7 and 9-14 are in condition for Allowance and respectfully request Notice of Allowance.

If a telephone conference would advance prosecution of this application, the Examiner is invited to telephone the undersigned at 973.660.7681.

Respectfully submitted,

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